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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/023,279	02/13/1998	JAY RUBINSTEIN	UIOWA-26	6755

34610 7590 03/20/2003

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EXAMINER

HARVEY, DIONNE

ART UNIT	PAPER NUMBER
2643	68

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/023,279	Applicant(s) Rubinstein
Examiner Dionne Harvey	Art Unit 2643



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above, claim(s) 14 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, 6-13, 15-22, and 24-31 is/are rejected.

7) Claim(s) 3-5 and 23 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 recites the limitation "the pseudospontaneous activity". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2,6-8,11,13,19,20,22,27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochmair (US 4,357,497).

Regarding claims 1 and 22,

Hochmair teaches a cochlear implant system, comprising: a signal generator (74) that generates a second signal(75); a signal processor(see figure 2) that combines a first signal(63,71) that represents sound and a second signal(75) having a frequency above approximately 2kHz, and therefore capable of causing pseudospontaneous activity (see page 14 of the Applicant's

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specification), to output a combined signal (76,78); and stimulation unit(see figures 10, elements 110,111,112) coupled to the signal processor that receives the combined signal from the signal processor. Hochmair teaches that the pulse repetition rate may vary and further teaches a carrier signal pulse train of 12 megahertz and 31 megahertz (column 5, lines 37-65).

Regarding claim 2,

In figure 5, Hochmair teaches that the stimulation unit is an electrode array(92) coupled to the auditory nerve (see column 6, lines 59-63).

Regarding claim 6

Since Hochmair teaches rapid state transitions and a frequency greater than 3kHz.

Regarding claim 7,

Shown in Figure 2, Hochmair teaches summing the first and second signals, as broadly claimed.

Regarding claim 8,

Hochmair teaches a microphone(52) that generates a first signal, the microphone being coupled to the signal processor (see figure 2).

Regarding claim 11,

The method of claim 11 is rejected for the same reasons set forth in the rejection of claims 1 and 22 as being inherently taught by the apparatus of claims 1 and 22.

Regarding claim 13,

Hochmair teaches that the first signal represents at least one of speech, emergency signals and control information.

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Regarding claim 19,

It appears that Hochmair teaches that applying the combined signal generates substantially continuous activity, thus permitting the sensation of hearing as disclosed in column 2.

Regarding claim 20,

Hochmair teaches that the second signal is not continuously applied.

Regarding claim 27,

Hochmair teaches that the prosthesis(90) is a cochlear implant applying current to the auditory nerve.

Regarding claim 28,

It appears that Hochmair teaches that the pseudo spontaneous activity continues after the second signal has stopped, thus permitting the sensation of hearing.

2. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Dormer (US Re 32,947).

Regarding claim 22,

Dormer teaches a neural prosthetic apparatus, comprising: a signal generator (36) that generates a second signal; a signal processor (34) that combines a first signal(30) that represents sound and a second signal(36) to output a combined signal; and stimulation unit(6) coupled to the signal processor that receives the combined signal from the signal processor for application to the

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auditory nerve, wherein the second signal includes at least fluctuations in amplitude greater than a prescribed amount at a frequency above approximately 2kHz (see column 4, lines 50-58).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9,10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochmair (US 4,357,497).

Regarding claims 9 and 15,

Hochmair fails to specifically teach that the signals are combined by adding, multiplying or an AND operator. However, the Examiner takes the Official Notice that the use of such operators when summing signals is well known in the art and it would have been obvious to one of ordinary skill in the art at the time of the invention to employ any one of a number of combining methods to transmit a plurality of signals.

Regarding claim 10,

Hochmair fails to specifically teach coupling between the stimulation unit and signal processor via wire. However, the Examiner takes the Official Notice that various wireless or wired coupling techniques for transmitting information are well known in the art and it would have been obvious

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to one of ordinary skill in the art at the time of the invention to substitute a coupling method which includes a lead wire of sorts for that of Hochmair, as an alternative method for coupling information between the processor and the implanted stimulator.

4. Claims 1,11,12,21,22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson (US 6,169,813).

Regarding Claims 1,11 and 22,

Richardson teaches a hearing aid, comprising: a signal generator (14) that generates a second signal(15); a signal processor(16) that combines a first signal(12) that represents sound and a second signal(15) having a frequency above approximately 2kHz, and therefore capable of causing pseudospontaneous activity (see page 14 of the Applicant's specification), to output a combined signal (17); and stimulation unit (18,20) coupled to the signal processor that receives the combined signal from the signal processor. Richardson does not specifically teach a cochlear implant. However, Richardson teaches that the applicator may be of any physical form suitable for application of a physical stimulus to the human body. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the invention to use a cochlear implant for the applicator of Richardson, since cochlear implants are well known in the art as being suitable for applying physical stimulus for improving speech perception.

Claim 12,

Richardson teaches applying the combined signal to the auditory nerve.

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Claim 21,

Richardson teaches that the second signal includes fluctuations in amplitude above 2k Hz.

Claims 24-26,

Richardson teaches a signal above 2k Hz and therefore teaches that the second signal generates independent activity in the nerve fibers.

Response to Arguments

5. Applicant's arguments filed 2/6/03 with regard to claims 1,11 and 22 have been fully considered but they are not persuasive.

Traversal of Hochmair

It is noted that there exists no point of contention on the part of the Applicant with regard to the Examiner's assertion that page 14 of the Applicant's specification defines pseudospontaneous activity as the resulting from delivery of a high rate pulse train directly to the auditory nerve. And, since Hochmair teaches a carrier signal pulse train of 12 megahertz and 31 megahertz (column 5, lines 37-65), Hochmair's second signal is capable of causing pseudospontaneous activity, as claimed.

The Applicant's primary reason for traversal of the Hochmair reference as prior art relates to the carrier signal, being indicated by the Examiner as the second signal capable of causing pseudospontaneous activity, is demodulated and therefore never reaches the cochlea.

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While the Examiner acknowledges this, the Examiner emphasizes that the Applicant has failed to specifically claim that the "cochlea" receives the combined signal of the claim. Instead, the claim language recites that a "stimulation unit" is the receptor for the combined signal. The "stimulation unit", which is a broader limitation than "cochlea" or "auditory nerve", is interpreted by the Examiner as being comprised of elements 110,111 and 112 in the Hochmair reference. Therefore, the claims are anticipated by the Hochmair reference, given the broadness of the limitations in the claim. Rejections of claims 1,11 and 22 over Hochmair are thus maintained.

Traversal of Dormer

The Applicant submits that the 16k Hz carrier signal of Dormer is removed by the second coil assembly 10. However, the Examiner submits that the Dormer reference makes no mention of a demodulating device included with the second coil assembly. Therefore, The Examiner interprets the device of Dormer as only including those elements clearly recited and supported by the specification, drawing and claims. The rejection over the Dormer reference is therefore maintained.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 16-18 and 29-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No. 6,078,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 14 are broader in scope than the claims of the immediate application.

Allowable Subject Matter

Claims 16-18 and 29-31 are allowed.

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Claims 3-5 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lippa (US 6,377,693) teaches two signal stimulation.

Dibachi (US 6,173,062) teaches two signal stimulation.

Lenhardt (US 5,047,994) teaches two signal stimulation of saccule.

Adelman (US 4,419,544) teaches firing of hair cells.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statements for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111. The examiner can normally be reached on Monday through Friday from 8:30am to 6:00pm.

Any responses to this action should be mailed to:

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Commissioner of Patents and Trademarks

Washington, DC 20231

or faxed to:

(703) 308-6306, for formal communications for entry

Or:

(703) 308-6296, for informal or draft communications, please label "PROPOSED" or
"DRAFT".

Hand delivered responses should be brought to Crystal Park II, 2121 Crystal Drive,
Arlington, VA., Sixth Floor(Receptionist)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Curtis Kuntz, can be reached at (703) 305-4708.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111.

D.H.



CURTIS KUNTZ
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